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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,936	09/23/2003	Michele Sanicola-Nadel	13751-045003	3298
26161	7590	04/18/2007	EXAMINER	
FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			HARRIS, ALANA M	
			ART UNIT	PAPER NUMBER
			1643	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		04/18/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/668,936	SANICOLA-NADEL ET AL.	
<b>Examiner</b>	<b>Art Unit</b>		
Alana M. Harris, Ph.D.	1643		

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

WHENEVER LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 29 January 2007.

2a)  This action is **FINAL**.                            2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## **Disposition of Claims**

4)  Claim(s) 1-13 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) 3-5 and 11-13 is/are allowed.

6)  Claim(s) 1, 2 and 6-10 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date

4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.

5)  Notice of Informal Patent Application

6)  Other: \_\_\_\_.

**DETAILED ACTION**

***Response to Arguments***

1. Claims 1-13 are pending.

Claims 1, 2 and 6-10 have been amended.

Claims 11-13 have been added.

Claims 1-13 are examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Priority***

3. Acknowledgment is made of applicant's claim for priority under 35 U.S.C. § 120 and 119(e). The Examiner has noted that the instant application is a divisional U.S. Serial No. 09/187,906, filed November 6, 1998, which is a continuation-in-part of PCT/US97/07726, filed May 7, 1997, which is a continuation-in-part of prior application U.S. Serial Number 60/017,427, filed May 8, 1996, which is a continuation-in-part of prior application U.S. Serial Number 60/019,300, filed June 7, 1996, which is a continuation-in-part of U.S. Serial Number 60/021,859, filed July 16, 1996, which is a continuation-in-part of U.S. Serial No. 60/043,533, filed April 11, 1997 from which priority is claimed. All of these documents were reviewed by the Examiner. **The limitations of all the sequences, SEQ. ID. NO: 17 and 21 are only disclosed in PCT/US/07726, filed May 7, 1997 and U.S. Serial No. 09/187,906, filed November 6,**

1998. Thus, claims 1-13 will not be granted the priority dates of all of the aforementioned provisional documents. Priority of all the claims will be granted the effective filing date of the PCT/US/07726, filed on May 7, 1997. This is the date that all sequence limitations of claims 1-13 in their entirety is found. Applicants are reminded that a claim as a whole has only one effective filing date, see e.g. Studiengelsellschaft Kahle m.b.H. v. Shell Oil Co. 42 USPQ2d 1674, 1677 (Fed. Cir 1997).

***Withdrawn Rejection***

***Claim Rejections - 35 USC § 112***

4. The rejection of claims 2 and 6 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of Applicants' response filed January 29, 2007.

***Maintained and New Grounds of Rejection***

***Claim Rejections - 35 USC § 112***

5. The rejection of claims 1, 2 and 6-10 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained.

Applicants aver the specification "...describes the identification and characterization of the human RetL3 protein (SEQ ID NO: 21) and the murine RetL3 protein (SEQ ID NO: 17)", see Remarks submitted January 29, 2007, page 4, 5<sup>th</sup>

paragraph. Applicants note the “[g]iven that each of the disclosed RetL3 proteins constitutes a functional polypeptide that interacts with the receptor tyrosine kinase Ret, the skilled person would readily expect that at least those amino acids that diverge between the two RetL3 species (i.e., 23.2% of the amino acid positions) are likely to be amenable to change without eliminating biological activity”, see page 4 of the Remarks. These points of view and arguments have been carefully considered, but found unpersuasive.

Applicants continue not to be in possession of all proteins that have reduced sequence homology to wild type proteins, SEQ ID NO: 17 and SEQ ID NO: 21. The written description in this case only sets forth Ret ligands as listed in claims 3-5 and 11-13. Applicants' specification continues not to provide sufficient evidence that they were in possession of the infinite number of polypeptides that include the denoted sequences. Applicants must disclose a representative number of species when claims read on an entire genus. When there is substantial variation with the genus, such as in the instant case one must describe a sufficient variety of species to reflect the variation within the genus, see 1242 Official Gazette 174, January 30, 2001. A genus that embraces widely variant species cannot be achieved by disclosing only one species with the genus. Applicants' claims embody a host of polypeptides, which has not been provided within the specification. Applicants seem to only be in possession of SEQ ID NO: 17 and 21. As noted in the first action on the merits (FAOM) mailed September 27, 2006 adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The polypeptide itself

is required known to definitively not eliminate biological activity. For the reasons of record the rejection is maintained.

6. The rejection of claims 1, 2 and 6-10 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is maintained.

Applicants argue “[i]t is well within the grasp of the biologist of ordinary skill to prepare a polypeptide that is at least 80% (or at least 90% or 95%) identical to the RetL3 sequence of SEQ ID NO:17 or SEQ ID NO:21”, see bridging paragraph of pages 6 and 7 of the Remarks. Applicants conclude their arguments noting “...one of ordinary skill in the art would have been able, at the time of filing of the present application, to make and use the claimed polypeptides without undue experimentation and with a reasonable expectation of success”, see page 8 of Remarks.

While Applicants' claims do note the function which must correspond with the claimed polypeptide, the claims continue to read on a number of polypeptides because remiss from the specification is sufficient guidance as to what amino acid residues and domains are tolerable to changes and would render polypeptides that would function in the manner that is germane to the implementation of the molecules. For the reasons of record the rejection is maintained.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

8. Claims 1, 2 and 6-10 are rejected under 35 U.S.C. 102(e) as being anticipated by United States Patent Application Publication number 2004/0235714 A1 (effective filing date April 22, 1996). The publication discloses sequences 42 and 38, which share at least 92% and 99% sequence homology with Applicants' SEQ ID NO: 17 and 21, respectively, see SCORE results, particularly the rapm and rapbm databases.

9. Claims 1, 2 and 6-10 are rejected under 35 U.S.C. 102(e) as being anticipated by United States Patent number 7,138,251 B1 (effective filing date April 22, 1996). The patent discloses sequences 42 and 38, which share at least 92% and 99% sequence homology with Applicants' SEQ ID NO: 17 and 21, respectively, see SCORE results, particularly the rapm and rapbm databases.

***Allowable Subject Matter***

10. Claims 3-5 and 11-13 are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571) 272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1643

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
ALANA M. HARRIS, PH.D.  
PRIMARY EXAMINER  
Alana M. Harris, Ph.D.  
16 April 2007